

In re Application of: Yoseph SHAALTIEL et al.
Serial No.: 10/554,387
Filed: October 25, 2005
Final Office Action Mailing Date: April 8, 2009

Examiner: Delia M. RAMIREZ
Group Art Unit: 1652
Attorney Docket: 30570

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 73-98, 100, 103, 106-109, 114, 115, 117, 120, 121 and 124-149 are pending in the Application. Claims 73-97, 103, 121 and 129-141 have been withdrawn from consideration. Claims 98, 100, 106-109, 114, 115, 117, 120, 124-128 and 142-149 have been rejected.

Claims 109, 120, 127 and 148 have been rejected under 35 U.S.C. §112. Claims 98, 100, 106-107, 114-115, 117, 124-125, 127, 128 and 146-149 have been rejected under 35 U.S.C. §103(a) as being obvious over Garger et al. in view of Boller et al. and Stomp et al. Claims 98, 100, 106-109, 114, 117, 120, 124-128 and 142-149 have been provisionally rejected under 35 U.S.C. §101 for non-statutory double patenting as claiming the same invention as claims of co-pending U.S. Patent Application No. 11/790,991. Claims 103, 108, 121, 126, 129-141 and 147-149 have now been canceled. Claims 98, 115, 127 and 146 have now been amended. New claims 150-153 have been added.

Specification

Regarding SEQ ID NO: 8: The Examiner has noted that in the amendment filed on February 17, 2009, the amino acid sequence of SEQ ID NO: 8 was found to contain a gap "around amino acid 287...". Applicants regret the unfortunate error in the amino acid sequence of SEQ ID NO: 8, as provided in the communication of February 17, 2009, and wishes to draw the Examiner's attention to the Second Supplemental Amendment (in response to Office Action dated July 21, 2008) filed on March 31, 2009, and received at the USPTO on April 2, 2009 (see Exhibits A and B), in which the correct amino acid sequence of SEQ ID NO: 8, according to all criteria, is provided. It will be noted that alignment of SEQ ID NO: 14, or the polypeptide encoded by SEQ ID NO:7, with now corrected SEQ ID NO: 8 shows a perfect alignment along the sequence of SEQ ID NO: 8. Thus, SEQ ID NO: 8, as provided in

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the communication of March 31, 2009, is identical to the polypeptide encoded by SEQ ID NO: 7 and comprised by SEQ ID NO: 14 as originally filed.

Thus, Applicants respectfully request cancellation and disregard of the SEQ ID NO: 8 as provided on February 17, 2009, and its replacement with the corrected SEQ ID NO: 8 provided on March 31, 2009.

In view of this amendment, Applicants submit that the new matter rejection on the basis of erroneous SEQ ID NO: 8, is overcome, and respectfully request withdrawal of any rejection of the specification and claims based thereupon.

35 U.S.C. §112, Second Paragraph Rejections

The Examiner has rejected claims 109, 120, 127 and 148 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the Invention. Claim 148 has now been canceled, rendering moot the Examiner's rejection thereof.

The Examiner has rejected claims 109 and 120 alleging that the protein recited in claims 98/115 cannot comprise the protein of SEQ ID NO: 8. Corrected SEQ ID NO: 8 has been provided with the communication of March 31, 2009, thereby obviating the rejection of claims 109 and 120 on the basis of 112, second paragraph.

Regarding claim 127- claim 127 has now been amended to recite:

"127. The plant cell preparation of claim 115, wherein the main glycan structure of the lysosomal protein of said plant cell preparation comprises at least one xylose residue and at least one exposed mannose residue, as measured by linkage analysis."

Thus, claim 127 now relates to the "*main glycan structure of the lysosomal protein*", as suggested by the Examiner.

Thus, Applicants believe to have overcome the rejections of claims 109, 120 and 127 on the basis of 35 U.S.C. §112, second paragraph.

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35 U.S.C. §112, First Paragraph Rejections

The Examiner has rejected claims 109, 120, 142 and 144 under 35 U.S.C. §112, First Paragraph, as failing to comply with the written description requirement. The Examiner's rejections are respectfully traversed.

The Examiner has rejected claims 109, 120, 142 and 144 as including subject-matter not adequately described in the specification, e.g. SEQ ID NO: 8 as provided in the communication of February 17, 2009. Applicants wish to direct the Examiner's attention to the corrected and accurate SEQ ID NO: 8 as provided in the communication of March 31, 2009, which attributes are detailed *supra*. Thus, Applicants respectfully request withdrawal of the 112, first paragraph rejection of claims 109, 120, 142 and 144.

35 U.S.C. §103 Rejections:

Garger et al. (U.S. Patent Application No. 09/993,059)
in view of Boller et al. (U.S. Patent No. 6,054,637) and
Stomp et al. (U.S. Patent No. 6,815,184).

The Examiner has rejected claims 98, 100, 106-107, 114-115, 117, 124-125, 127, 128 and 146-149 under 35 U.S.C. §103(a) as allegedly being unpatentable over Garger et al. in view of Boller et al and Stomp et al. The Examiner's rejections are respectfully traversed. Claims 103, 108, 121, 126, 129-141 and 147-149 have now been canceled, rendering moot the Examiner's rejections thereof. Claims 98, 115, 127 and 146 have now been amended.

In order to expedite prosecution in this case, claims 98 and 115 have now been amended to include the limitation of now canceled claims 108 and 126, directed to the ER signal being the amino acid sequence as set forth in SEQ ID NO: 1.

Further, claim 146 has now been amended to include the limitations of:

- i) a human glucocerebrosidase (SEQ ID NO: 8);
- ii) at least one terminal mannose residue;
- iii) a C-terminal vacuolar targeting signal peptide; and

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iv) an N-terminal endoplasmic reticulum signal peptide (SEQ ID NO: 1).
Insasmuch as the Examiner has indicated that claims 108 and 126 read on novel and non-obvious subject-matter, Applicant submits that independent claims 98, 115 and 146, and claims depending therefrom are now in condition for allowance. Withdrawal of the 103 rejection is respectfully requested.

Double Patenting

The Examiner has rejected claims 98, 100, 106-109, 114-115, 117, 120, 124-128, and 142-149 under 35 U.S.C. §101 on the grounds of provisional double patenting as being obvious over the invention of claims 39 and 45 of co-pending U.S. Patent Application No. 11/790,991. Claims 103, 108, 121, 126, 129-141 and 147-149 have now been canceled, rendering moot the Examiner's rejections thereof.

Issues of provisional and obviousness-type double-patenting and the submission of a terminal disclaimer will be further considered upon indication of allowable subject-matter.

New Claims

New claims 150-153, directed to methods for producing the lysosomal protein of claim 98 have been added. Claims 150-153 are claims directed to means for producing the lysosomal protein of claim 98 by culturing a plant cell preparation comprising the protein as defined in claim 98. Inasmuch as the inventions of amended claims 98 and 115 are now deemed novel and non-obvious, claims 98 and 115 now constitute linking claims for rejoicing previously withdrawn claims directed to means of production of the lysosomal protein, (for example, now canceled claims 129-131) which were withdrawn by election in response to the Restriction Requirement dated April 7, 2008.

Claim 150 relates to a method for producing the human lysosome glucocerebrosidase of claim 98 by culturing a plant cell preparation. Claim 151 is a dependent claim defining the preparation as being the preparation of claim 115.

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Claim 152 is a dependent claim in which the cell culture is cultured in suspension.
 Claim 153 further includes purifying the protein.

Corresponding Patent Applications

Applicants wish to make of record the Office Action issued by the USPTO on September 26, 2008 in co-pending U.S. Patent Application No. 11/790,991. All the material references cited in the '991 application have been made of record in the subject application. Applicants believe that they have fully complied with the Federal Circuit court's concerns raised in *McKesson Information Solutions v. Bridge Medical, Inc.* 82 U.S.P.Q.2D (BNA) 1865 (2007).

In view of the foregoing amendments and remarks, pending claims 98, 100, 106, 107, 109, 114, 115, 117, 120, 124, 125, 127, 142-146, and new claims 150-153 are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Respectfully submitted,

Martin D. Moynihan
 Registration No. 40,338

Date: August 3, 2009

Enclosures:

- Request for Continued Examination (RCE);
- Petition for Extension of Time (One Month);
- Exhibit A: Copy of Second Supplemental Amendment in response to Office Action dated July 21, 2008 as filed on March 31, 2009; and
- Exhibit B: Official Stamp Sheet for Second Supplementary Amendment (in response to Office Action dated July 2008) as stamped on April 2, 2009 by the US Patent and Trademark Office



EXHIBIT A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

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Yoseph SHAALTIEL et al

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Serial No.: 10/554,387

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Filed: October 25, 2005

Group Art Unit: 1652

For: PRODUCTION OF HIGH
MANNOSE PROTEINS IN
PLANT CULTURE

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Group Art Unit: 1652

Examiner: Delia M. Ramirez

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Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SECOND SUPPLEMENTAL AMENDMENT

Sir:

This second Supplemental Amendment is being made voluntarily, and follows the first Supplemental Amendment filed on February 17, 2009, which was filed following the Response submitted on December 22, 2008, to the Office Action mailed July 21, 2008.

REMARKS

In the first Supplemental Amendment filed on February 17, 2009, Applicants regretfully noticed a small error was made in the amino acid sequence as set forth in SEQ ID NO: 8, rendering it inaccurate (for example, as compared with the translation of the coding sequence as set forth in SEQ ID NO:7 or the glucocerebrosidase sequence contained in residues 23 to 519 of SEQ ID NO: 14).

Enclosed herein please find a corrected SEQUENCE listing, which differs from the SEQUENCE listing currently on file solely in the composition of amino acid sequence of SEQ ID NO: 8, which has now been corrected to include the entire amino

acid sequence of human glucocerebrosidase, identical to the translated coding sequence as set forth in SEQ ID NO: 7.

Please replace the SEQUENCE listing on record in the present application with the corrected SEQUENCE listing provided herein in computer readable and paper forms.

As detailed in the previous communication, Applicant maintains that this replacement SEQUENCE listing does not constitute introduction of new subject-matter.

STATEMENT

The content of the paper and computer readable form are the same and include no new matter.

Examiner's consideration of this second Supplementary Amendment is respectfully requested. Please notify the undersigned upon entrance of this second Supplementary Amendment into the record.

Respectfully submitted,

Martin D. Moynihan
Registration No. 40,338

Date: March 31, 2009

Enclosures:

- Replacement Sequence listing



EXHIBIT B

APPLICANT : Yoseph SHAALTIEL et al

DOCKET NO. : 30570

APPLICATION NO.: 10/554,387

FILED : October 25, 2005

FOR : PRODUCTION OF HIGH MANNOSE
PROTEINS IN PLANT CULTURE

Receipt of the following papers is acknowledged by the
U.S. Patent & Trademark Office as evidenced by the Mail Room Stamp:

SECOND SUPPLEMENTAL AMENDMENT/
9 PAGES OF SEQUENCE LISTING + FLOPPY DISC

